REMARKS

Careful consideration has been given by the applicant to the Examiner's comments and rejection of the claims, as set forth in the outstanding Office Action, and favorable reconsideration and allowance of the application, as amended, is earnestly solicited.

Applicant notes the Examiner's rejection of the claims and the further discussion as to previously cited Walker, U.S. Patent No. 5,330,533, although the present rejection is based on Walker and further newly cited prior art, as represented by Roger, et al., U.S. Patent No. 5,935,173, and wherein the Examiner also refers to previously submitted French Patent Millon, FR 2 621 243, which was submitted by the present applicant in an Information Disclosure Statement.

Concerning the foregoing, applicant has noted the Examiner's rejection of Claims 7-21 under 35 U.S.C. §112, first paragraph, and also in view of the second paragraph in that the materials are considered to be obvious and ceramic is not disclosed. Furthermore, applicant notes the Examiner's minor formal objections with regard to terminology in the claims. Accordingly, in order to clearly obviate the formal grounds of rejection under 35 U.S.C. §112, first and second paragraphs, applicant has deleted reference to the various materials throughout the claims, inasmuch as this is an aspect which is not essential to an understanding of the invention and the claims are directed to patentable features, as elucidated hereinbelow, and which the type of materials are not an essential aspect.

Furthermore, the claims have also been amended in formal respects to provide appropriate antecedent terminology, as requested by the Examiner, thereby meeting all of the formalities set forth in the Office Action.

Concerning the rejection in view of the prior art, applicant notes the previous reference to Walker, U.S. Patent No. 5,330,533 and the rejection of Claims 7-21 under 35 U.S.C. §102(b) as being anticipated by Walker, as detailed in the Office Action.

Furthermore, applicant notes the rejection of Claims 7-12 and 15-21 under 35 U.S.C. §102(b) as being allegedly anticipated by Millon, French Patent No. 2 621 243; and also the rejection of Claims 7-21 under 35 U.S.C. §103(a), as being unpatentable over newly cited Roger, et al., U.S. Patent No. 5,935,173 in view of Walker, U.S. Patent No. 5,330,533, as extensively detailed in the Office Action.

However, it is clearly apparent that the Examiner has erroneously interpreted the prior art in its applicability to the present invention and that the claims, as amended and presented herein, are clearly and patentably distinct over the references, irrespective as to whether the latter are considered singly or in combination.

In addition to again reverting to the arguments as previously submitted, applicant notes that Walker, contrary to the Examiner's comments, does not disclose a spiral curve in a sagittal plane. In particular, the definition of a spiral-shaped femoral component in the sagittal plane indicates that a spiral relates to a curve with a continuous variation of the radius when the component moves in rotation. Thus, when rotation varies in a minute aspect, so as to be practically infinitesimally small, the radius various then such that the variation is

continuous. However, as set forth and disclosed in Walker and also newly cited Rogers, et al. and the state of the prior art as currently known in the technology, in which the curve in the sagittal plane is a two radius curve there is encountered a discontinuous variation of the contact between the femoral component and the insert. Reverting to the drawings of Walker and, particularly, Figures 3B and 3C thereof, there is illustrated a superior view from the anterior lateral direction of the upper part of the femoral component. Consequently, this essentially oblique view does not permit anyone to conclude as to any geometric shape, and precisely fails to disclose a spiral shape in a sagittal plane.

The embodiment, as described in Walker, is essentially directed to the following:

As described in column 1, lines 21 and 22, "the femoral component, which alters the sagittal radius"; furthermore, in column 1, lines 36 and 41, there is described the "femoral component having a bearing surface whose radius in each sagittal section... is substantially constant from posterior to a point more anterior than the distal most point"; in column 1, lines 49 and 52, "the tibial bearing, when viewed in one or more sagittal sections has a radius of curvature which substantially corresponds with the radius of the bearing surface of the femoral component". Consequently, it is clearly apparent that none of the embodiments in the description of Walker, U.S. Patent No. 5,330,533, in any manner relate to or disclose a spiral shape in the sagittal plane. This novel concept is the primary aspect and the important advantage of the present inventive prosthesis, and is in no manner disclosed, nor suggested in the prior art.

Furthermore, the prior art also fails to describe the spiral curve of the femoral component (spi F), which is associated with a spiral curve of the insert (spi T), the spi T being one part or a segment of the spi F (femoral component).

In column 4, lines 44-63, Walker describes that "the condylar surfaces of the femoral component in Figure 3a wherein the condylar surfaces resemble the anatomical. Anatomy refers to flats, notches and so forth; whereas the femoral component in Figure 3C illustrates essentially the same concept in Walker. This is clearly contrary to the provision of a spiral shape in a sagittal plane, as presented and claimed in the present application.

The foregoing is also applicable to newly cited Roger, et al., U.S. Patent No. 5,935,173, who describe the classical shape of a femoral component in the sagittal plane with two radii R1 and R2. This clearly indicates a discontinuity in contact when the femoral component is rolling in the insert during flexion of the joint or prosthesis. Consequently, Roger, et al. is completely incapable of providing a spiral curve in a sagittal plane analogous to that set forth and claimed in the present application. This drawback is also applicable to the French patent to Millon.

Neither in Walker, nor in Roger, et al., are there described shapes, which are of a spiral curve configuration. To the contrary, all of the shapes in the prior art are either constant radius, cylindrical, anatomic or providing surfaces with two radii, which is a discontinuous aspect of the surface, and are clearly contrary to the description of a spiral shape in a sagittal plane.

In order to obviate the alleged applicability of the prior art, and to clearly distinguish thereover, all of the claims in the present application have been amended so as to indicate that the femoral component has a spiral radius in a sagittal plane (spi F) with the insert also possessing a spiral shape in a sagittal plane (spi T) with the spiral spi T being a segment of the spiral spi F in the portion where the curvature of both components are complementary to each other so as to provide the mutual surface contact in a unique and advantageous spiral shape configuration of movement.

Furthermore, the applicant has appropriately set forth the absence of any discontinuities, sharp edges and flats, and the Examiner's comments that the term "or flats" renders the limitation in the alternative are deemed inapplicable. However, in order to obviate this particular point, applicant has modified the terminology so that this indicates the absence of discontinuities, flats and sharp edges for both the femoral component and for the insert at any location and in any direction, any plane both sagittal or frontal. The applicant notes that this aspect, which has now been incorporated into the claims, as clearly supported by the specification, further distinguishes over the prior art, irrespective as to whether the latter is considered singly or in combination. Although the frontal plane in Walker appears generally to show a drawing figure (3b) in which the insert has an undulating curve without sharp edges, flats and discontinuities, this cannot be considered to be in the sagittal plane 35, (which is the insert in the drawings of Walker) in that the insert is either an anatomical, cylindrical or is flattened in shape.

In essence, referring to Walker at column 4, lines 48 et seq. "The femoral shape (anatomical or cylindrical) is then used to computer generate a tibial surface 35 (corresponding to the insert 35) based on input laxity requirements in internal posterior displacement and internal-external rotation. This clearly implies that there is a flattening of the insert in order to permit A/P and rotational movements between the components (femoral component and insert).

In essence, none of the presently claimed features referring to a spiral curve in a sagittal plane can be found in Walker.

With regard to Roger, et al., applicant further notes that the lateral cavities 21 and the convex lateral parts 14, 15 are flat in a frontal plane, as shown in Figures 2 and 4. In the sagittal plane in Roger, et al., the components possess a curve with two radii, which is a discontinuous curve, and thereby clearly contrary to a spiral curve, which is continuous from 0° to 140° flexion. In both Roger, et al. and Walker, the increased contact does not automatically indicate or signify that there are no flats or edges or discontinuities. In effect, neither of these patents, whether considered alone or in combination, discloses a spiral shape for both components, in essence for the femoral component and also the insert.

With regard to Millon, French Patent No. 2 621 243, Walker and the prior art in general, in Millon the femoral component has only a point contact with the insert in the central part, but not in the lateral condylars. Further contact can be conceivably due to the wear of the plastic material, however, this is contrary to what the present invention is directed to by providing the spiral curve in a sagittal plane.

Basically, all known knee prostheses possess the following general shape: two condyles; one medial; one lateral with a downward look in convexity lying in two lateral cavities of a plastic insert concavely facing upwardly; a central part of the femoral component being hollow and a central part of the plastic insert with convex upward facing configuration; whereas in the sagittal plane, the femoral component has generally a polycentric shape, (R1, R2 and occasionally R3) in effect a plurality of radii providing a discontinuity and in the frontal plane, there are generally encountered flats and/or discontinuities and/or sharp edges.

In order to avoid the foregoing, the inventive configuration of the knee prosthesis has in the sagittal plane a spiral curve for a femoral component and also for the insert. In this connection, the spiral curve of the insert is in correlation with the spiral curve of the femoral component over at least a portion of the extent thereof. All of the sagittal planes of the femoral component and of the insert posses these spirally curved properties.

There are no flats, sharp edges, or discontinuities encountered at any point and in any plane of the femoral component and of the insert and at any contact surface between the femoral component and the insert pursuant to the invention. Walker is incapable of providing the foregoing configuration inasmuch as there is evident the flattening of his insert by A/P movement of the femoral component.

Due to the rolling displacement of the spiral F femoral component and the spiral T (insert) during the flexion movement of the knee, the contact point between the femoral component in the insert as viewed in a sagittal plane, is some millimeters in front of the center

of the tibial component surface in extension and moves some millimeters rearwardly of the center of the tibial component in flexion. This is set forth in present Claim 11.

In essence, all of the claims as presented herein, are uniquely directed to the spiral shape of the femoral component in the sagittal plane, following from medial to lateral on an undulating sinusoidal-like curve in the frontal plane, and with the spiral shape of the insert in the sagittal plane following a sinusoidal-like curve in the frontal plane.

In addition to the foregoing, applicant encloses an Appendix X showing sketches of drawing figures (4 sheets) illustrative of the explanation thereof as set forth hereinbelow, further emphasizing the physical and operative distinctions between the present invention and the prior art:

Thus, with regard to the foregoing, referring to the attached Appendix, in Figure 1 there is illustrated a spiral, which shows an infinity of radii, therefore, providing no discontinuities, sharp edges and/or any flats. This is clearly not the instance in the prior art.

Figures 2A and 2B, as attached, illustrates the present invention in which Figure 2A illustrates the femoral component and the plastic insert in a sagittal view. The configuration of the femoral component is a spiral (A) and the configuration or shape of the plastic insert is also a spiral (B) in the sagittal plane. Thus, when the femoral component moves on the plastic insert during knee flexion, the spiral A rolls in the spiral B. As a consequence, there are encountered an infinity of contact surfaces and always a conformity between the femoral component and the plastic insert. Referring to Figure 2B of the invention, this shows the contact zone between the femoral component and the plastic insert of the present construction.

With regard to Figures 3A and 3B, these illustrate the configurations of both Rogers, et al. and Walker.

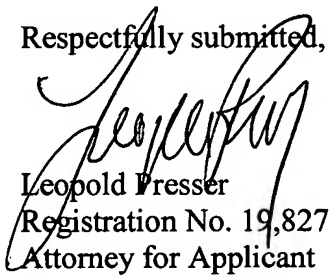
Thus, Figure 3A illustrates an example of Roger, et al.'s design wherein the femoral component has two or more radii and the plastic insert has one of these radii, for example, R1. Thus, when the femoral component rotates through a knee flexion, there is a discontinuity zone when the contact zone passes from R1 to R2.

Referring to Figure 3B, this discloses essentially the Walker design in which the shape of the femoral component is either cylindrical or anatomic (no precise shape, and in general indicating a multiplicity of separate radii). There is never disclosed nor suggested a geometric spiral in the sagittal plane. The shape of the plastic insert is either flattened by anterior posterior laxity input A/P movements of A and B, or possibly may also represent a cylinder and which rotates within a cylinder, which has nothing in common with the present invention.

In summation, inasmuch as the currently presented claims clearly and unambiguously distinguish over the art, irrespective as to whether the latter is considered singly or in combination, the present application is clearly directed to allowable and patentable subject matter, and the favorable reconsideration and early issuance of the Notice of Allowance by the Examiner is earnestly solicited.

However, in the event that the Examiner has any queries concerning the instantly submitted Amendment, applicant's attorney respectfully requests that he be accorded the courtesy of possibly a telephone conference to discuss any matters in need of attention.

Respectfully submitted,



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Enclosures: Appendix A